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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,300	06/23/2006	Yoshinori Amano	2006_1022A	9011
52349 7590 06/08/2010 WENDEROTH, LIND & PONACK L.L.P. 1030 15th Street, N.W. Suite 400 East Washington, DC 20005-1503			EXAMINER MA, JAMESON Q	
			ART UNIT 1797	PAPER NUMBER
			NOTIFICATION DATE 06/08/2010	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ddalecki@wenderoth.com  
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<b>Office Action Summary</b>	<b>Application No.</b> 10/584,300	<b>Applicant(s)</b> AMANO ET AL.	
	<b>Examiner</b> JAMESON Q. MA	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2009 and 03 March 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-71 is/are pending in the application.
- 4a) Of the above claim(s) 9, 16, 23-55, and 62-71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-15, 17-22, and 56-61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/15/06, 9/11/08</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Claims 9, 16, 23-55, and 62-71 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected groups and species, there being no allowable generic or linking claim. Election was made **without** traverse in the replies filed on 10/30/09 and 3/3/10.
2. Applicant's election of group I, species A, and species 1 in the replies filed on 10/30/09 and 3/3/10 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

### ***Information Disclosure Statement***

3. The remaining references cited in the International Search Reports have been considered and are considered no more pertinent to the instant claims than the references listed below.

### ***Specification***

4. The disclosure is objected to because of the following informalities: pages 9-37 of the specification refer to specific claims. The references to specific claim numbers should be removed.

Appropriate correction is required.

***Claim Objections***

5. Claim 1 is objected to because of the following informalities: the word 'the' appears to be misspelled as 'tae.' Appropriate correction is required.
6. Claims 12 and 59 are objected to because the word 'pin' appears to be misspelled as 'pint.' Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
8. Claims 8 and 58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
9. Claims 8 and 58 are indefinite because it recites the limitation 'a heater for measuring a temperature of the first channel with a thermistor.' It is unclear if the claim requires both a heater and a thermistor. For examination purposes, the device is interpreted to comprise both elements,

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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11. Claims 1-4, 8, 21, 56, 58, and 61 are rejected under 35 U.S.C. 102(b) as being anticipated by Mian et al. (US 2001/0055812).

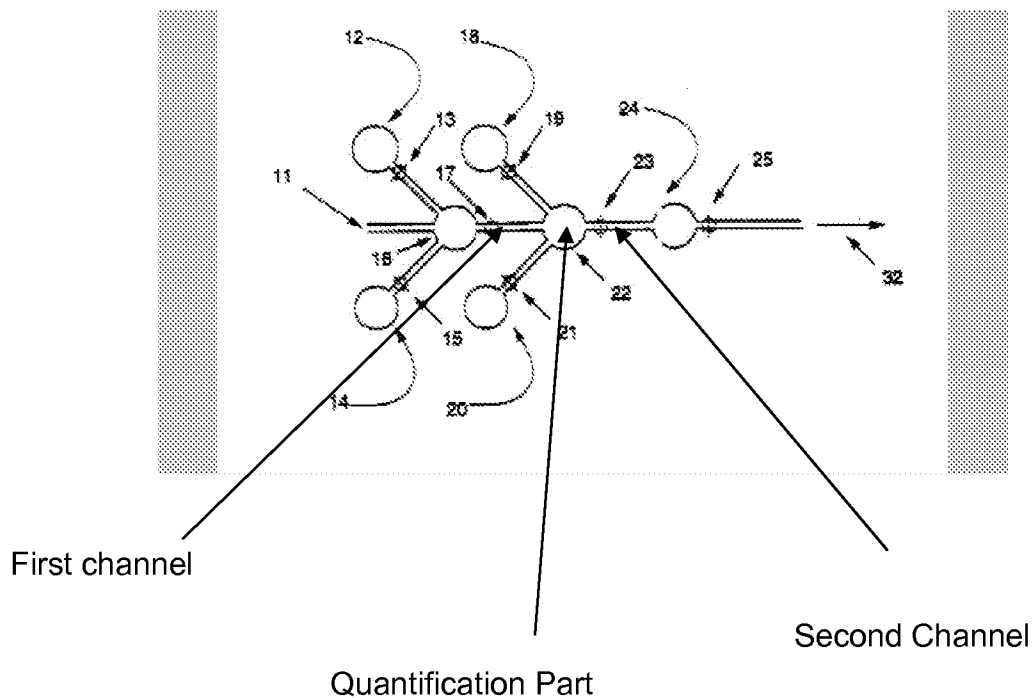
The Mian reference has been interpreted two separate ways to reject the following claims. These interpretations have been designated as Interpretation 1 and Interpretation 2. The Mian reference has been interpreted generically with regard to the following limitations regarding a 'plate' and 'channel':

Regarding claim 1, Mian discloses a plate (see figs. 1A-1C and [0051]: Microsystems on a disk) on which a channel pattern is formed, said channel pattern comprising a first channel into which a buffer agent is injected, and a second channel having, in a portion thereof, a quantification part that has a portion common to the first channel.

The channels are fully capable of holding a predetermined amount of a biological sample, said biological sample being injected into the channel including the quantification part. It is noted that these limitations are viewed as materials worked on by the claimed apparatus. Neither the manner of operating a disclosed device nor material or article worked upon further limit an apparatus claim. Said limitations do not differentiate apparatus claims from prior art. See MPEP § 2114 and 2115. Further, it has been held that process limitations do not have patentable weight in an apparatus claim. See *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969) that states

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“Expressions relating the apparatus to contents thereof and to an intended operation are of no significance in determining patentability of the apparatus claim.”



#### Interpretation 1:

For this interpretation, the loader from figs. 13A-13C and [0215], is viewed as a filling unit capable of filling a buffer agent into the first channel of the plate while filling a biological sample into the second channel including the quantification part, and thereafter, making a predetermined amount of the biological sample remain in the quantification part of the second channel to add the predetermined amount of the biological sample to the buffer agent.

For this interpretation, the micromanipulation device (see [0044], [0170], and figs. 14A-14E) is viewed as a discrimination unit capable of making a predetermined amount

of the biological sample that is held in the quantification part migrate in a buffer agent to discriminate the biological sample that migrates in the buffer agent.

Interpretation 2:

For this interpretation, the micromanipulation device (see [0044], [0170], and figs. 14A-14E) is viewed as a filling unit capable of filling a buffer agent into the first channel of the plate while filling a biological sample into the second channel including the quantification part, and thereafter, making a predetermined amount of the biological sample remain in the quantification part of the second channel to add the predetermined amount of the biological sample to the buffer agent.

For this interpretation, the loader from figs. 13A-13C and [0215] is viewed as a discrimination unit capable of making a predetermined amount of the biological sample that is held in the quantification part migrate in a buffer agent to discriminate the biological sample that migrates in the buffer agent.

The following dependent claims are rejected under Interpretation 2.

For claim 2, Mian discloses the apparatus wherein said plate has a buffer agent injection part connected to the first channel (one of the reservoirs 12, 14, 18, or 20), a sample injection part connected to the second channel (one of the reservoirs 12, 14, 18, or 20). Alternatively, port 11 is viewed as a buffer agent injection part and a sample injection part. Mian further discloses an air hole (see [0107]: air displacement channels) connected to the sample injection part in the second channel, and said filling unit is capable of rotating the plate (see [0043]),

The limitation 'in which the buffer agent is injected into the buffer agent injection part and the sample is injected into the sample injection part, thereby to make the buffer agent stored in the buffer agent injection part flow into the first channel by a centrifugal force, and simultaneously, make the biological sample stored in the sample injection part flow up to a first flow position that does not reach the quantification part in the second channel' is viewed as intended use of the claimed device. A recitation directed to the manner in which a claimed apparatus is intended to be used does not distinguish the claimed apparatus from the prior art, if the prior art has the capability to so perform.

The manipulation device which rotates the sample is viewed as capable of pressurizing the sample injection part (see [0049]: fluid transport by means of centripetal acceleration would result in a pressurization of the sample inlet port). The limitation 'to make the biological sample in the second channel flow from the first flow position up to a second flow position including the quantification part in the second channel, and thereafter, rotates the plate to separate the biological sample in the second channel so that a predetermined amount of the biological sample remains in the quantification part of the second channel' is viewed as intended use of the claimed device. A recitation directed to the manner in which a claimed apparatus is intended to be used does not distinguish the claimed apparatus from the prior art, if the prior art has the capability to so perform.

For claim 3, Mian discloses the device with a plate with injection parts and air hole which is capable of rotation and is capable of rotation and pressurization as



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disclosed above. Further, the device is capable of performing aspiration from the air hole. (see [0107]).

For claims 4 and 56, the manipulation device comprises a motor (see [0170]), whose controller is also viewed as a pressure control part (see [0170]).

For claims 8 and 58, Mian discloses both a heater and a thermistor (see [0150]). It is unclear from the claims if there is a limitation regarding the orientation of the heater and the thermistor. If so, Mian still discloses that thermal devices can be applied to the disk as a whole or in specific areas on the disk (see [0150]) which is viewed to meet the instant claim limitation.

For claims 21 and 61, the discrimination unit includes an optical detector (see figs. 14A-14F: photodiode). The optical device is viewed as capable of 'discriminating the biological sample on the basis of the result of detection.'

### ***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 5, 8, 10-11, 14-15, 17, 22, 57 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mian et al. (US 2001/0055812).

Mian discloses all of the claim limitations as set forth above.

Interpretation 2 is used to reject the following claims.

For claims 5, 22, and 57, Mian discloses (see figs. 13A-14F) that the manipulation device (filling unit) is at a lower part of the apparatus than the loader (discrimination unit). Additionally, as is evident from the same figures and [0215] there must be some vertical displacement between the disk and the loader. It is not explicitly disclosed that the optical detector is disposed on an elevation stage (implying that the manipulation device has a height adjustment unit for vertical displacement). However, since vertical displacement is required for the device to operate, and since there are only two components that can accomplish this displacement, it would have been obvious to one of ordinary skill in the art at the time of invention to configure the

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manipulation device of Mian to perform the displacement, because the exact placement of the vertical displacement mechanism (elevation stage) would have been nothing more than an engineering design choice, which was identified by Mian, obvious to one of ordinary skill in the art at the time of invention barring any unexpected results arising from the exact placement of the vertical displacement mechanism (elevation stage) within device.

This rejection of claim 8 is in the alternative to the one above.

For claims 8 and 10-11, Mian discloses both a heater and a thermistor (see [0150]). It is unclear from the claims if there is a limitation regarding the orientation of the heater and the thermistor. If so, Mian still discloses that thermal devices can be applied to the disk as a whole or in specific areas on the disk (see [0150]). If the exact placement claimed is not viewed to be explicitly met by Mian, the exact placement of the heating devices would have been nothing more than an engineering design choice, which was identified by Mian, obvious to one of ordinary skill in the art at the time of invention barring any unexpected results arising from the exact placement of the heating elements within device.

For claims 14 and 60, Mian discloses that electrophoresis is performed and explicitly discloses the placement of the positive electrode (see [0321]). While the reference does not explicitly disclose the negative electrode, for gel electrophoresis to occur, a negative electrode must be present in order for the necessary electric field to be generated. With respect to the exact placement of the electrodes, exact placement of the heating devices would have been nothing more than an engineering design

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choice, which was identified by Mian, obvious to one of ordinary skill in the art at the time of invention barring any unexpected results arising from the exact placement of the electrodes in the device.

For claim 15, any portion of the plane of the disk is viewed as a 'cleaning portion and the remaining limitations to the electrodes being cleaned are viewed as intended use of the claimed device.

For claim 17, the limitations to the sample and buffer agent are regarded as materials worked on. Neither the manner of operating a disclosed device nor material or article worked upon further limit an apparatus claim. Said limitations do not differentiate apparatus claims from prior art. See MPEP § 2114 and 2115. Further, it has been held that process limitations do not have patentable weight in an apparatus claim. See *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969) that states "Expressions relating the apparatus to contents thereof and to an intended operation are of no significance in determining patentability of the apparatus claim."

16. Claims 2-3, 12-13, and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mian et al. (US 2001/0055812) in view of Miyake et al. (US 5,174,162).

Mian discloses all of the claim limitations as set forth above.

This rejection of claims 2-3 is in the alternative to the one above

Interpretation 1 is used to reject the following claims:

Regarding claims 2 and 3, Mian does not disclose that the loader from figs. 13A-13C and [0215], viewed as the filling unit, is capable of rotating the plate and has a

motor. However, Mian does disclose in fig. 13C a multiple loader for the disk which is in a radial arrangement.

Miyake discloses a pipetting system in a radial arrangement wherein six sets of pipetters are equally spaced in a radial arrangement. The pipetters move along a circumferential path picking up reagents, depositing them into an analyzer, and then are moved to a washing station (see C7L42-C8/L31). Miyake discloses that the disc (40) rotates and that the apparatus comprises a rotor and that the means for moving the disc 40 are not shown.

It would have been obvious to one of ordinary skill in the art at the time of invention to incorporate the pipetting system of Miyake into the loading device of Mian in order to allow pipettes to pick up reagents, deposit them, and then be washed in a continuous manner as taught by Miyake.

While modified Mian (Miyake) does not disclose a motor on the filling unit, it is interpreted that a motor must be present in order to effect the rotation of the disc (40) disclosed by Miyake.

Modified Mian discloses all of the structural limitations required by claims 2 and 3 as the filling unit is now capable of rotating a plate.

Alternatively, assuming *arguendo* that no motor is disclosed, it would have been obvious to one of ordinary skill in the art at the time of invention to use a motor as the means for effecting rotation of disc (40) because would have been to select the most efficient and controllable means for effecting rotation of a disk.

Regarding claims 12, 13, and 59 the manipulation device (discrimination unit), has a fitting pin (see figs. 14A-14F: the projection where the disk rests on the manipulation device is a fitting pin), and the plate has a fitting hole (see figs. 14A-14F: the disk is a compact disk with an aperture in its center). The plate (disk) is intended to be fixed to the discrimination unit (mating of the disk and manipulation device), and as disclosed above, the manipulation device has a motor which rotates. Further, the photodiode of the manipulation device (figs. 14A-14F) is viewed as fully capable of acting as a positioning mark detection sensor for detecting a mark provided on the plate.

17. Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mian et al. (US 2001/0055812) in view of Tang (US 2002/0183000).

Regarding claims 18-20, Mian discloses all of the claim limitations as set forth above. Additionally, Mian is generally directed to analysis wherein microfluidic channels are incorporated to a structure resembling a compact disc and is spun/analyzed by suitable spinning means as discussed above.

The reference does not explicitly disclose a fan.

Tang discloses that fans are used in compact disc drives (see [0002]). Tang further discloses a fan with baffles (26A, 26B, 28A, and 28B, viewed as L-shaped: see [0051]). Additionally, Tang discloses that effective fan filter units are needed to keep particle contents within clean rooms at acceptable levels and to circulate the air (see [0002]). The fan of Tang comprises a filter (see [0034] and [0051]). A 'film' here is

interpreted to be a thin sheet of any material and since the filter (32) filters out air particles it is thus a 'porous film.'

It would have been obvious to one of ordinary skill in the art at the time of invention to incorporate the fan of Tang into the compact disc spinner of Mian in order to allow for filtration of air and cooling of the device.

18. Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mian et al. (US 2001/0055812) as applied to claims 5, 8, 10-11, 14-15, 17, 22, 57 and 60 above, and further in view of Shimizu (US 2002/0014191).

Regarding claims 6-7, modified Mian discloses all of the claim limitations as set forth above.

The reference does not explicitly disclose that the loader (discrimination unit) is hung via a spring from a ceiling board.

However, as is evident from the same figures and [0215] there must be some vertical displacement between the disk and the loader.

Shimizu discloses a hollow needle which is capable of vertical displacement via a coil compression spring (357, see [0294]).

It would have been obvious to one of ordinary skill in the art at the time of invention to vertically displace the multiple loader of modified Mian with a coil spring as taught by Shimizu because doing so would have allowed for a known exemplary and controllable method for raising and lowering a syringe/needle/pipette device. Additionally, for claim 7, the loaders themselves are viewed as pressure control units.

***Conclusion***

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMESON Q. MA whose telephone number is (571)270-7063. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Marcheschi can be reached on (571)272-1374. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JM  
June 3, 2010

/Michael A Marcheschi/  
Supervisory Patent Examiner, Art  
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